UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

In re: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	)	MDL No. 1456 Civil Action No. 01-12257-PBS
THIS DOCUMENT RELATES TO:	)	Hon. Patti B. Saris
United States of America ex rel. Ven-a-Care of the Florida Keys, Inc., v. Boehringer Ingelheim Corp., et al., Civil Action No. 07-10248-PBS	)	***Docket# 83 Motion for Leave to File was granted on November 25, 2008***

REPLY BRIEF IN SUPPORT OF UNITED STATES' MOTION FOR LEAVE TO FILE AMENDED COMPLAINT

The party opposing a motion to amend a complaint must show that the amendment will result in unfair prejudice. See Carmona v. Toldeo, 215 F.3d 124, 136 (1st Cir. 2000) (without showing of prejudice, delay alone is not a reason to disallow amendment); Dennis v. Dillard Dep't. Stores, Inc., 207 F.3d 523, 528 (8th Cir. 2000); Lorenz v. CSX Corp., 1 F.3d 1406, 1414 (3rd Cir 1993) (describing "prejudice to the non-moving party" as the "touchstone for the denial of an amendment"). Because the Roxane defendants fail to show how amending the complaint to include three additional National Drug Codes ("NDCs") relating to *a drug already at issue in the litigation* will cause them prejudice, the Motion to Amend should be allowed.

In opposing the Motion to Amend, the Roxane defendants rely heavily on statements made by this Court when ruling on the United States' motion to amend its complaint against Abbott Laboratories to include an entirely new drug, Acyclovir. See Roxane Defendants' Opposition to United States' Motion for Leave to File Amended Complaint ("Opposition"), 5. The instant motion presents a different set of considerations – and much less possibility for prejudice – because the proposed amendment relates only to new NDCs for drugs already at issue. Crucially, the Roxane

defendants do not dispute that (1) the NovaPlus Products that the United States seeks to add to its complaint are identical to the ipratropium bromide products already included in the complaint, and (2) that Roxane followed substantially similar pricing strategies for both its NovaPlus and ordinary ipratropium bromide products. In similar circumstances in the New York Counties case, this Court allowed plaintiffs to amend their complaint to include new NDCs for drugs already at issue in litigation. See Memorandum In Support of United States' Motion for Leave to File Amended Complaint ("Motion to Amend"), Exhibit 3.

The Roxane defendants assert two reasons why the proposed amendment would be prejudicial: first, it would "require Roxane and the Government to subpoena and depose Novation employees regarding Novation's marketing of NovaPlus" and, second, it would require the parties to "re-depose multiple Medicare carriers in order to determine the potential effect (if any) that the NovaPlus NDCs had on Medicare payments for ipratropium bromide." See Opposition, 9-10. Neither reason stands up to scrutiny.

There is no reason for any Novation employee to be deposed. As the defendants note, the gravamen of the United States' complaint is that the Roxane defendants caused the Medicare and Medicaid programs to pay inflated reimbursement on Roxane drugs in order to makes such drugs more attractive to Roxane's customers. With regard to the NovaPlus Products, Roxane reported Average Wholesale Prices ("AWPs") that were exactly the same as the AWPs Roxane reported for its ordinary ipratropium bromide products. See Motion to Amend, Exhibit 2. Roxane sold the NovaPlus products to Novation's membership at prices substantially lower than the reported AWPs,

and largely similar to the prices Roxane charged for its ordinary ipratropium bromide products.[1] See Opposition, Exhibit B, ROXMA036538-39, ROXMA036541-42, ROXMA036544, and ROXMA036633. Evidence of how Novation marketed the products to its members is irrelevant; the only relevant conduct is whether *Roxane* created a reimbursement spread for the NovaPlus products, and whether Roxane marketed that spread to Novation.

There is also no need for any "Medicare carrier" to be re-deposed. Of the four Medicare Durable Medical Equipment Regional Carriers ("DMERCs"), three have been deposed already (with a Roxane attorney attending each deposition), and Roxane had ample opportunity to depose the fourth if it wished. In addition, all relevant documents regarding how the DMERCs reimbursed for the NovaPlus and ipratropium bromide products have been produced. These documents show with mathematical precision exactly how the DMERCs set reimbursement amounts for Roxane drugs – including the NovaPlus Products. The methodology used by the DMERCs for establishing the reimbursement amounts has been exhaustively addressed in the DMERC depositions, and Roxane cannot point to any testimony or evidence suggesting that the DMERCs' reimbursement methodology varies on an NDC by NDC basis.

Accordingly, because the Roxane defendants can show no prejudice resulting from the proposed amendment, the United States' Motion to Amend should be allowed.

[1] In fact, the prices Roxane charged to Novation were in general lower than the prices it charged for its ordinary ipratropium bromide products (thus resulting in even larger spreads than on Roxane's ordinary ipratropium bromide products). See Opposition, Exhibit B, ROXMA036538-39, ROXMA036541-42, ROXMA036544, and ROXMA036633

Respectfully submitted,

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Dated: December 2, 2008

CERTIFICATE OF SERVICE

I hereby certify that I have this day caused an electronic copy of the above REPLY BRIEF AND MEMORANDUM IN SUPPORT OF UNITED STATES' MOTION FOR LEAVE TO FILE AMENDED COMPLAINT to be served on all counsel of record via electronic service pursuant to the Case Management Order by sending a copy to LexisNexis File & Serve for posting and notification to all parties.

/s/ James J. Fauci
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Dated: December 2, 2008